

Subpart K—Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims

SOURCE: 57 FR 49408, Nov. 2, 1992, unless otherwise noted.

§ 456.700 Scope.

This subpart prescribes requirements for—

(a) An outpatient DUR program that includes prospective drug review, retrospective drug use review, and an educational program;

(b) The establishment, composition, and functions of a State DUR Board; and

(c) An optional point-of-sale electronic claims management system for processing claims for covered outpatient drugs.

§ 456.702 Definitions.

For purposes of this subpart—

Abuse is defined as in § 455.2 of this chapter.

Adverse medical result means a clinically significant undesirable effect, experienced by a patient, due to a course of drug therapy.

Appropriate and medically necessary means drug prescribing and dispensing that is in conformity with the predetermined standards established in accordance with § 456.703.

Criteria is defined as in § 466.1 of this chapter.

Fraud is defined as in § 455.2 of this chapter.

Gross overuse means repetitive overutilization without therapeutic benefit.

Inappropriate and medically unnecessary means drug prescribing and dispensing not in conformity with the definition of *appropriate and medically necessary*.

Overutilization means use of a drug in a quantity, strength, or duration that is greater than necessary to achieve a desired therapeutic goal or that puts the recipient at risk of a clinically significant undesirable effect, or both.

Predetermined standards means criteria and standards that have been established in accordance with the requirements of § 456.703.

Standards is defined as in § 466.1 of this chapter.

Underutilization means use of a drug by a recipient in insufficient quantity, strength, or duration to achieve a desired therapeutic goal or that puts the recipient at risk of a clinically significant undesired effect, or both.

[57 FR 49408, Nov. 2, 1992, as amended at 59 FR 48824, Sept. 23, 1994]

§ 456.703 Drug use review program.

(a) *General.* Except as provided in paragraphs (b) and (c) of this section, in order for FFP to be paid or made available under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a DUR program consisting of prospective drug review, retrospective drug use review, and an educational program that meets the requirements of this subpart. The goal of the State's DUR program must be to ensure appropriate drug therapy, while permitting sufficient professional prerogatives to allow for individualized drug therapy.

(b) *Exception for drugs dispensed to certain nursing facility residents.* Prospective drug review and retrospective drug use review (including interventions and education) under the DUR program are not required for drugs dispensed to residents of nursing facilities that are in compliance with the drug regimen review procedures set forth in part 483 of this chapter. This does not preclude the State agency from making such drugs subject to prospective DUR or retrospective DUR or both, provided the State agency makes the drugs subject to all the requirements of this subpart applicable to the respective review.

(c) *Exemption for certain covered outpatient drugs dispensed by hospitals and health maintenance organizations.* (1) The State plan must provide that covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the plan at no more than the hospital's purchasing costs are not subject to the requirements of this subpart. Individual hospitals requesting this exemption must provide assurances to the State agency that they meet the requirements specified in section 1927(j)(2) of the Act.